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Medical Devices, The new normal

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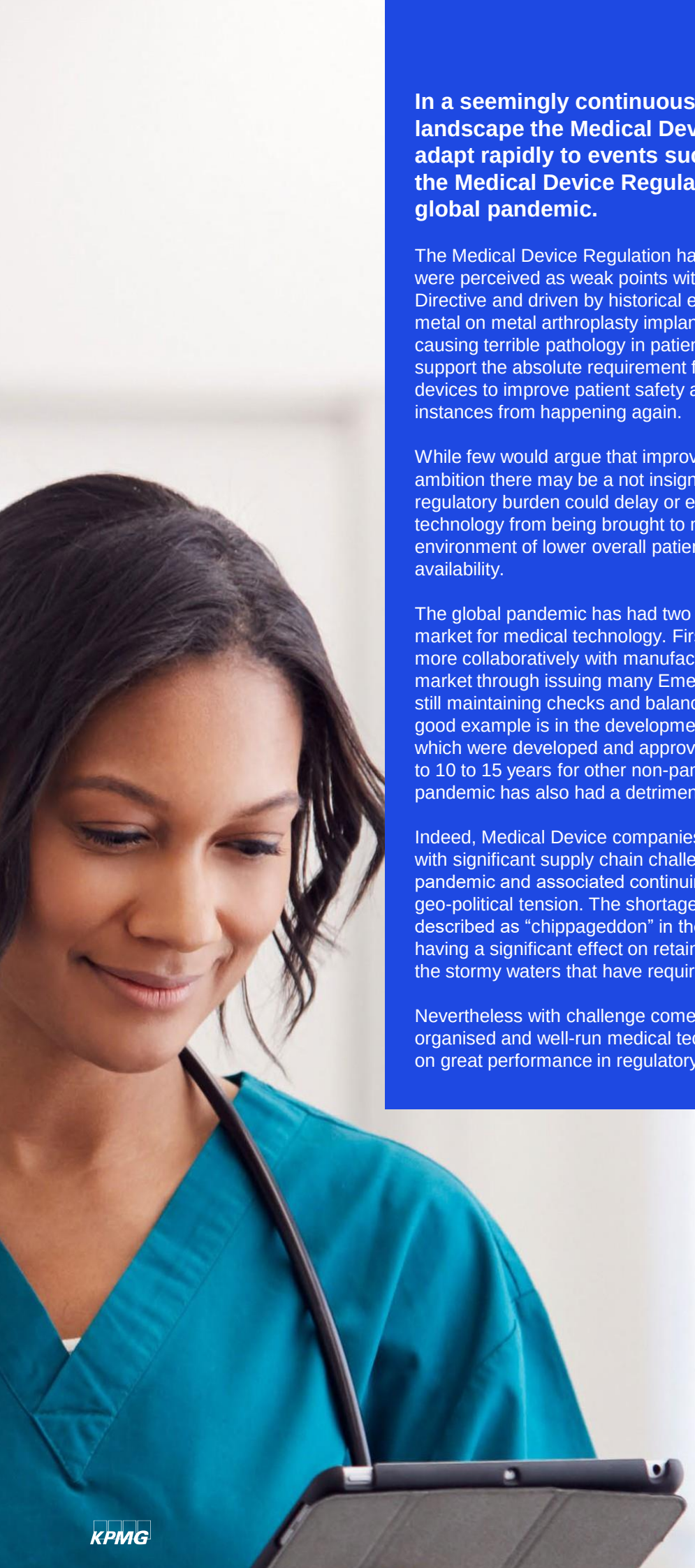

In a seemingly continuously changing regulatory landscape the Medical Devices industry has had to adapt rapidly to events such as the introduction of the Medical Device Regulation, (EU) 2017/745 and the global pandemic.

The Medical Device Regulation has been developed to address what were perceived as weak points within the previous Medical Device Directive and driven by historical events such as issues related to metal on metal arthroplasty implants and silicone breast implants causing terrible pathology in patients. These two events very clearly support the absolute requirement for increased regulation of medical devices to improve patient safety and protect against these types of instances from happening again.

While few would argue that improving patient safety is not a worthy ambition there may be a not insignificant risk that increasing regulatory burden could delay or even prevent innovative medical technology from being brought to market thereby creating an environment of lower overall patient safety through reduced availability.

The global pandemic has had two opposing influences on time to market for medical technology. Firstly, regulators were able to work more collaboratively with manufacturers and fast-tracked devices to market through issuing many Emergency Use Authorisations whilst still maintaining checks and balances to maintain patient safety. A good example is in the development of the first SARS-CoV-2 vaccines which were developed and approved for use within a year, compared to 10 to 15 years for other non-pandemic vaccines. However, the pandemic has also had a detrimental effect on supply chain efficiency.

Indeed, Medical Device companies find themselves in turbulent times with significant supply chain challenges brought about not just by the pandemic and associated continuing “lockdowns” but also increasing geo-political tension. The shortage of semiconductor chips frequently described as “chippageddon” in the press and the “great resign“ having a significant effect on retaining talent, are just two examples of the stormy waters that have required careful navigation.

Nevertheless with challenge comes opportunity for the prepared, organised and well-run medical technology entities, as they capitalise on great performance in regulatory, supply chain and people.

Market financials – growth sectors

In 2022 it was expected that the global medical devices market would return to stable single-digit growth, with the projection that orthopaedics & prosthetics would be the fastest-growing product area, which we are seeing play out with the return of elective procedures in post pandemic regions and the increased levels of morbidity in growing populations, with high growth in fragility fractures such as hip fracture as an example of the types of indications driving this statistic. Supply chains remain affected globally by both the pandemic, the conflict in Ukraine and the ongoing energy and resources situation.

Diversification of medical device production supply chains has been required which is starting to take effect and we see some positive strengthening of supply chains across all industries.

The lowering global rates of COVID and therefore reduction in testing rates in 2022 is starting to effect revenue and growth of many diagnostics manufacturers, after previous impressive performances related to the previous needs of the pandemic.

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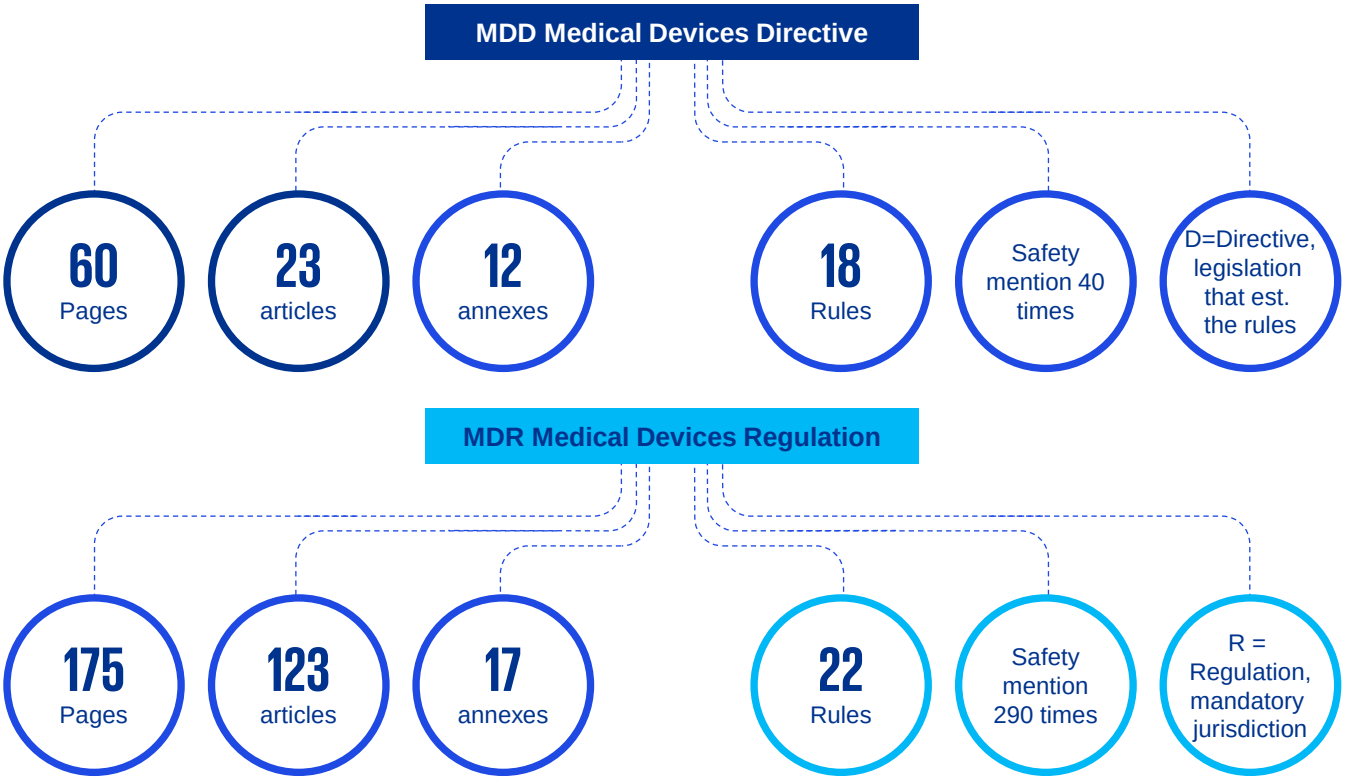
Mid-Year Update: Medical Devices Key Themes For 2022 (fitchsolutions.com)

In the last decade the UK has experienced a lost decade of Life Sciences investment from successive governments while the US has continued to dominate followed by an ever-growing China. Ireland is noteworthy with very high investment in Life Sciences with per capita, one of the leading countries globally following a strong policy of high investment in this area.

Product launch considerations

The new regulatory landscape is shaping both how strategy is formed for the launch of new products and the formation of new companies planning to bring innovation into the market. Previously the European Union's CE pathway for device clearance under the Medical Device Directive (MDD) was generally regarded as a less- demanding route than clearing into the US for example. As a result, organisations often targeted a European launch initially while continuing to generate additional data to support device submissions in more highly regulated markets. This strategy often allowed early revenue generation to support the gathering of more detailed submission data. For example, MDD enabled new products to simply utilise predicate data of clinically and materially similar devices already on the market therefore reducing the requirement for lengthy and costly clinical studies prior to launch. Under MDR, depending on device classification, the requirements to provide clinical data are much more stringent leading to a longer and more costly submission process.

The following schematic diagram (Fang Consulting) gives an overview of the differences and highlights some of the changes between the Medical Device Directive and the medical Device Regulation



Big MDD-MDR changes

- Classification rules
- Post Market Surveillanc/Vigilance
- Clinical Evidence – Much stricter requirements to prove patient and user safety
- Increased role and more defined instructions for Economic Operators

Medium MDD-MDR Changes

- Enhanced Quality Management System required
- Traceability – Eudamed & UDI System implementation
- More detailed requirements for Technical Documentation (including GSPR)

Smaller MDD-MDR Changes

- Increased scope and definition of a Medical Device
- PRRC – Person Responsible for Regulatory Compliance

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MDD to MDR – The Why, What and How of the Approaching Transition - Fang Consulting

The well-documented lack of Notified Body capacity brought about by changes in regulation necessitating more data from more devices to examine, consequences of the pandemic, slower than expected availability of guidance (amongst other issues), is an important further consideration for a manufacturer wishing to pursue European market entry.

We find the EU at the beginning of the third quarter of 2022, with less than 18 months to go until the end of the grace period for MDD to MDR transition, and companies are still faced with major decisions on whether to obsolete devices from the market that may not be compliant on time. Many companies would argue that this is not due to a lack of planning but is a consequence of the Notified Body capacity constraints.

The French and German industry associations SNITEM and BVMed (together representing approximately 50% of the EU's medical device market) issued a paper in March 2022 calling for the grace period for MDR products to be extended by two years from 2024 to 2026 for the highest risk class products (Class III and implantables) and by four years, from 2024 to 2028, for all other devices.

These associations are concerned about a potential collapse in patient care due to lack of availability of devices and they noted that the average duration of the certification process is approximately 18 months. Furthermore at the time the paper was issued less than 5% of certificates have been transferred from MDD to MDR.

The two industry associations argue that the structure underpinning the MDR is not ready. More time is needed to create a fully functioning system so that the medtech industry, which is ready and waiting to prove the conformity of its products with the MDR, can take the necessary steps.

It is interesting to note that in August 2022 the MDCG issued a 19-point position paper listing actions designed to help improve the efficiency of the work of Notified Bodies. The position paper covers three categories encompassing steps to increase NB capacity, improving access to NBs and other steps that could be taken to ease the transition to the MDR.

For NB capacity the MDCG has suggested that NBs consider conducting, what they call "hybrid audits" a model that has become almost second nature during the pandemic. The initiatives also go on to advise auditors to exercise pragmatism and sensibility in terms of application of regulation to safe and effective legacy devices.

Although very welcome the guidance appears to be relatively subjective and quite open to interpretation, however, it remains to be seen whether the guidance will protect patient safety by helping to maintain device availability by relieving the bottlenecks to successful transition to MDR.

Product launch

UK Regulatory Framework

Currently the UK (with the exception of Northern Ireland) operates under the framework of the UK Medical Device Regulation 2002 which is based on the European Regulations (MDD and IVDD). For now devices carrying the CE mark are accepted onto the UK market until the end of June 2023 when manufacturers must use the UK Conformity Assessment resulting in “UKCA” marked devices.

A consultation with stakeholders was established on future direction that occurred towards the end of 2021 and in June 2022 the MHRA published the Government’s response to the consultation on the future regulation of medical devices in the UK. New regulations are expected in July 2023 but as Peter Ellingworth (Chief Executive, Association of British HealthTech Industries) expressed recently there is industry concern on the short time left for a successful switch to a new framework. It would therefore be wise to consider "extending unilateral recognition to other trusted jurisdictions such as the US and others who are part of existing internal collaborations." *(Financial Times 13 October 2022).*

It will not have escaped MHRA’s notice that some parts of MDR (and IVDR) implementation have gone well while in other areas some hurdles remain to be overcome to ensure smooth transition and widespread device availability. Indeed, while the Government’s response to the consultation indicates that proposed changes will broadly realign the UK closer to the EU regulations the response also states that the proposals will align the UK to international best practice in areas where the existing regime is recognised as being deficient. In general, divergence with the EU regime is where necessary for the protection of UK patients.

More specifically the response approves of a staged transition to the new framework, so that devices which are either UK Conformity Assessed or CE marked may remain on the market until their certificates expire or for a period of three to five years, dependent upon device classification, whichever is sooner.

Additionally, it seems likely that software (“Software as a Medical Device”) and in particular the use of Artificial Intelligence (AI) and Machine Learning (ML) within medical devices will be regarded as an important area with the UK Government publishing a policy paper in July 2022 entitled Establishing a pro innovation approach to regulating AI.

The MHRA is increasing its international collaboration efforts with an announcement in June 2022 that it is joining both the International Medical Device Regulatory Forum and the Medical Devices Innovation Consortium. Further partnership is also possible if UK regulators take the further step of moving from official observer status to full membership of the Medical Device single Audit Program (MDSAP), designed to allow easier market access to the commercially important countries of USA, Australia, Japan, Brazil and Canada. This step could go some way to improving the perception that the UK is a favourable region for innovative medical device technology development and launches.

There has been strong innovation in the space of robotics and its capacity as a technology to lessen the economic burdens of ever-growing numbers requiring elective, high-volume procedure such as hips and knee arthroplasty and the associated improvement on operating room efficiency and labour burdens. Moreover, nearly all the main arthroplasty players moving over the last few years to offer some level of robotic platform to strengthen its portfolio offering and with this comes extended regulatory requirements including those for software as a medical device (SaMD) and cyber security, which have their own fast-changing global regulatory landscapes. One particular area of note is on the subject of artificial intelligence (AI) and machine learning where in January 2021 the US FDA published *Artificial Intelligence/Machine Learning (AI/ ML)-Based Software as a Medical Device (SaMD) Action Plan* in direct response to feedback from stakeholders. The publication aims to provide practical oversight and future considerations the FDA will make for AI/ML based Medical Devices. In the publication FDA highlights six considerations including Good Machine Learning Practice (GMLP).

Many applications utilised in the operating room to assist with procedure planning and implantation of medical devices such as AI powered augmented reality navigation systems will find themselves requiring not only regulatory clearance for the medical device implant such as a pedicle screw for the spine but also for the software and AI system which is also subjected to the added governance of local and global cyber security laws.

Developments in regeneration, bespoke and bio- implants in orthopaedic pathologies will also continue to see innovation and be increasingly appealing to acquirers.

Summary

Due to the pandemic numerous Medical Device companies experienced a drop in performance mainly due to changing priorities in the health sector, and many choose to diversify into other areas driven by necessity. Now, the recovery has led to many feeling newly emboldened

to innovate and evolve further. Some Medical Device companies are in a position where they have utilised the fallow period to streamline and strengthen their infrastructure and supply chains. They now move with confidence into this new normal of tighter regulations, limited resources and a need for innovation. Those that may not have planned adequately may well be left behind.

Businesses willing to embrace these changes head on will reap the biggest benefits and attract the most attention from investors.

And as we look beyond the pandemic, I'm hopeful that the attention that life sciences in general have gathered from outside the sector continues, both to help firms innovate and grow and ultimately to drive better outcomes for patients and the general population.

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